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| 09/982,264 | 10/17/2001 | Bo Qiu | 271/288 | 8577 |
| 34055 | 7590 | 06/22/2004 | EXAMINER | |
| PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208 | | | DEVI, SARVAMANGALA J N | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,264

Applicant(s)

QIU ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-60 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 32-60 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12904</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election

1) Acknowledgment is made of Applicants' election of invention I and election of species, filed 04/30/04 in response to the restriction requirement and election of species requirement mailed 03/16/04. Applicants have elected invention I, claims 31-51, and the epitope combination species, SEQ ID NO: 4 plus SEQ ID NO: 7. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Preliminary Amendment

2) Acknowledgment is made of Applicants' preliminary amendment filed 01/29/04. With this, Applicants have amended the specification.

Status of Claims

3) Claims 1-30 have been canceled via the preliminary amendment filed 01/29/04.
New claims 31-60 have been added via the preliminary amendment filed 01/29/04.
Claims 31-60 are under prosecution.
Claims 31-51 have been elected.
Claims 52-60 are withdrawn from consideration as being directed to a non-elected invention.
Claims 32-51 are withdrawn from consideration as being directed to non-elected epitope combination species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.
Claim 31 is under examination. An action on the Merits for this claim is issued.

Sequence Listing

4) Acknowledgment is made of Applicants' raw sequence listing which has been entered on 03/05/02.

Information Disclosure Statement

5) Acknowledgment is made of Applicants' Information Disclosure Statement filed 01/29/04. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

6) The instant application claims priority to the provisional application, 60/242,819, filed 10/24/2000.

Amendment to the structure of SEQ ID NO: 4

7) It is noted that the amino acid sequence of the peptide, OspC1O, AA 198-207, SEQ ID NO: 4 has been amended via the preliminary amendment filed 01/29/04. Applicants state that the amendment is intended to correct a typographical error made by typing the residue 'W' in place of 'VV' at position 2 of the peptide OspC1O, AA 198-207. Applicants point to the last sentence on page 321 and Table 1 of the reference of Qiu *et al. Biopolymers (Peptide Science)* 55: 319-333, 2000, as providing the correct structure of SEQ ID NO: 4, and state that this is not new matter because the reference of Qiu *et al. Biopolymers* 55: 319, 2001 was incorporated by reference in the specification, as originally filed. The Qiu *et al.* article is submitted with the information disclosure statement filed 01/29/04. Based on Applicants' assertion that the sequence amendment is purely typographical in nature and based on the fact that it is reasonably conceivable for one to mistakenly type 'VV' as a 'W', the amendment has been accepted.

Specification - Informalities

8) Instant specification is objected to for the following reason(s):

(a) The amendment to the specification filed 01/29/04 is objected to under 35 U.S.C. § 132, because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows. On page 23, Applicants have added the section 'Brief Description of the Drawings'. The description for Figure 1 includes the phrase 'amino groups capable of attaching peptides to the copolymer'. However, there appears to be descriptive support for such a phrase in the specification, as originally filed. The Figure 1 legend on the drawing as submitted originally included the phrase 'amino groups for peptide attachment' and mentioned nothing about amino groups being capable of attaching peptides to the copolymer. Applicants are required to cancel the new matter in the response to this Office Action.

(b) It is unclear why some words or phrases in the specification are underlined. For example, see lines 23-25 on page 1; lines 23-25 on page 3; and line 12 on page 1. Brackets or underlining are commonly used to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent. It is unclear whether the underlining is intended to appear in the patent.

(c) The use of the trademarks in the instant specification has been noted in this application. For example, see pages 12, 13 and 16: 'MilliQ'; page 16 and 17: 'Superdex-75'; and pages 12 and 9: 'Tween 20'. Although the use of trademarks is permissible in patent applications, the propriety nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

(d) The amendment introduced 01/29/04 at line 7 of page 1 of the specification includes the recitation: 'This application claims priority from and Bo QIU *et al.*, which is incorporated by reference in its entirety herein'. It is unclear whether 'Bo QIU *et al.*' represents an unidentified co-pending application or an unidentified published or non-published reference article. If it is a reference article, the recitation is improper since a patent application cannot claim priority to a reference article. Clarification/correction is requested.

Rejections under 35 U.S.C § 101

9) 35 U.S.C. § 101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

10) Claim 31 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claim 31, as written, does not sufficiently distinguish over epitopes as they exist naturally in or on naturally occurring *Borrellia burgdorferi*, because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claim should be amended to indicate the hand of the inventor, e.g., by insertion of the term 'isolated' in reciting the active ingredients in the claimed composition as is described in the instant specification. See MPEP 2105.

Rejection(s) under 35 § U.S.C. 112, First Paragraph

11) Claim 31 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 31, includes the limitations: 'composition comprising *Borrelia burgforferii* epitopes SEQ ID NO: 4 and SEQ ID NO: 7'. Applicants point to page 2, lines 16-289; page 13, line 19 through page 15; and page 16, line 10 through page 21, line 9 of the specification as providing descriptive support for these limitations. However, these portions of the specification do not provide descriptive support for a composition which comprises the specific epitope combination claimed, i.e., *Borrelia burgforferii* epitopes SEQ ID NO: 4 and SEQ ID NO: 7. Claims as originally filed claimed an individual 'epitope polypeptide', and did not include the particular combination of '*Borrelia burgforferii* epitopes SEQ ID NO: 4 and SEQ ID NO: 7'. Furthermore, SEQ IDNO: 4 and SEQ ID NO: 7 are described in the originally filed specification as 'peptides', not as 'epitopes'. Therefore, the new limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or invited to point to specific pages and line numbers in the specification where support for such recitations can be found.

Rejection(s) under 35 § U.S.C. 112, Second Paragraph

12) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

13) Claim 31 is rejected under 35 § U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 31 is vague and indefinite in the recitation "epitopes SEQ ID NO: 4 and SEQ ID NO: 7", because it is unclear whether SEQ ID NO: 4 and SEQ ID NO: 7 represent nucleotide sequences, polypeptide sequences, or peptide sequences. If the latter is intended, it is suggested that Applicants amend the claim to indicate that SEQ ID NO: 4 and 7 are --amino acid sequences--.

Rejection(s) under 35 § U.S.C. 102

14) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15) Claim 31 is rejected under 35 § U.S.C. 102(b) as being anticipated by Gilmore *et al.* (*Infect. Immun.* 64: 2234-2239, 1996).

It is noted that the recited *Borrellia burgdorferi* epitopes in the claim are not required to be isolated or purified.

The transitional limitations “having”, “comprising”, “including”, “containing”, or “characterized by,” represent open-ended claim language and therefore, do not exclude additional, unrecited elements. See MPEP 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”). Therefore, the limitation “comprising” in the instant claim(s) allows additional elements or antigens to be present in the composition. It should be noted that the transitional phrase “consisting of” excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“consisting of” defined as “closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.”).

Gilmore *et al.* taught a composition comprising whole cells, cell lysates and gel fractionated proteins of *Borrellia burgdorferi*, strain B31. The cell lysate composition comprises OspC and the P39 protein antigens, which are immunoreactive with OspC-specific and P39-specific antibodies. See Figure 1; Materials and Methods on page 2235; and Results on page 2236. Since the claimed composition is not required to be purified, it is anticipated by the prior art cell lysate which comprises both immunoreactive OspC and P39 antigens. These two antigens of *Borrellia burgdorferi* are viewed as inherently comprising the recited epitopes of SEQ ID NO: 4 and SEQ ID NO: 7.

Claim 31 is anticipated by Gilmore *et al.*

Remarks

16) Claim 31 stands rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER